UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

ELIZABETH A. RECUPERO, Derivatively on Behalf of OSIRIS THERAPEUTICS, INC.,) Index No:
31 Marron Ave.) VERIFIED SHAREHOLDER
Stoughton, MA 02072) DERIVATIVE COMPLAINT
Stoughton, WA 02072) <u>DERIVATIVE COMI LATIVI</u>
Plaintiff,))
VS.) DEMAND FOR JURY TRIAL
PETER FRIEDLI,)
c/o Osiris Therapeutics, Inc.)
7015 Albert Einstein Dr.)
Columbia, MD 21046)
Columbia, MD 21040)
YVES HUWYLER,)
c/o Osiris Therapeutics, Inc.)
7015 Albert Einstein Dr.)
Columbia, MD 21046)
Columbia, WID 21040)
JAY M. MOYES,)
c/o Osiris Therapeutics, Inc.)
7015 Albert Einstein Dr.)
Columbia, MD 21046)
Columbia, WD 21040)
THOMAS M. BRANDT,)
c/o Osiris Therapeutics, Inc.)
7015 Albert Einstein Dr.)
Columbia, MD 21046)
Columbia, WD 21040)
Defendants,)
Defendants,)
and)
and)
OSIRIS THERAPEUTICS, INC.)
7015 Albert Einstein Dr.)
Columbia, Howard County, MD 21046)
c/o The Corporation Trust Inc.)
351 West Camden Street)
Baltimore, MD 21201,)
Danimore, MD 21201,) }
Nominal Defendant.)

Plaintiff ("Plaintiff"), by and through her undersigned counsel, derivatively on behalf of Nominal Defendant Osiris Therapeutics, Inc. ("Osiris" or the "Company"), submits this Verified Shareholder Derivative Complaint (the "Complaint"). Plaintiff's allegations are based upon her personal knowledge as to herself and her own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff's counsel, including a review of publicly available information, including filings by Osiris with the U.S. Securities and Exchange Commission ("SEC"), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

NATURE OF THE ACTION

- 1. This is a shareholder derivative action brought in the right, and for the benefit, of Osiris against certain of its officers and directors seeking to remedy Defendants' breach of fiduciary duties, gross mismanagement and unjust enrichment that occurred between May 12, 2014 to the present (the "Relevant Period") and have caused substantial harm to Osiris.
 - 2. Osiris was incorporated in 1992 and is based in Columbia, Maryland.
- 3. Throughout the Relevant Period, Defendants made materially false and misleading statements regarding the Company's business, operational and financial information. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that (i) the Company overstated revenues from several contracts and failed to follow the generally accepted accounting principles ("GAAP") standards, causing millions of dollars in losses to the Company; and (ii) as a result of the foregoing, the Company's public statements were materially false and misleading.
- 4. On November 16, 2015, the Company disclosed that it had "determined to correct the revenue recognition for three contracts which will result in a decrease in product revenues of \$1.8 million in the first quarter of 2015, a decrease in product revenue of \$1.0 million in the second

quarter, an increase in product revenues of \$0.8 million in the third quarter of 2015 and a decrease in product revenues of \$1.1 million in 2014." The Company restated figures from its 2014 Form 10-K and Forms 10-Q for the quarters ended March 31, 2015 and June 30, 2015. These restatements removed over \$3 million of sales and shifted another \$3.9 million in sales between the quarters.

- 5. The Company also disclosed that it had a material weakness in internal control over financial reporting and that its disclosure controls and procedures were not effective for each of the affected quarters. The announcement came after the Company had previously disclosed in its Form 10-Q for the quarter ending September 30, 2015 that it had undertaken a review of the timing of revenue recognition under contract with distributors.
- 6. On November 17, 2015, the Company's shares fell over 20% to close at \$10.97 per share. The Company's share price never recovered from the loss of trust created by Defendants' false and/or misleading statements.
- 7. In December 2015, the Company announced that its independent auditor, BDO USA, LLP ("BDO") resigned and "advised that their opinion on the effectiveness of the Company's internal controls over financial reporting as of December 31, 2014 should no longer be relied upon due to management's identification of a material weakness in internal controls over financial reporting related to the timing of revenue recognition under certain distribution contracts."
- 8. The fallout at the Company continued, as Lode Debrabandere abruptly resigned as Chief Executive Officer ("CEO") in February 2016. Debrabandere's departure followed that of Philip R. Jacoby Jr. who had resigned as the Company's Chief Financial Officer ("CFO") in September 2015.

- 9. On March 15, 2016, it was disclosed that the SEC is conducting a non-public investigation relating to the Company's historic accounting practices.
- 10. On May 27, 2016, the Company disclosed that it is the subject of a criminal investigation by the. U.S. Attorney's Office for the Southern District of New York. The U.S. Attorney's investigation is in connection with the Company's historic accounting practices.
- 11. The Company has been damaged as a result of Defendants' knowing breaches of fiduciary day and other misconduct.

JURISDICTION

- 12. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a)(1) because complete diversity exists between Plaintiff and each defendant, and the amount in controversy exceeds \$75,000.00 exclusive of interest and costs. This action is not a collusive one designed to confer jurisdiction upon a court of the United States that it would not otherwise have.
- 13. This Court has jurisdiction over each defendant because each defendant is either a corporation that conducts business in and maintains operations in this District or is an individual with sufficient minimum contacts with this District so as to render the exercise of jurisdiction permissible under traditional notions of fair play and substantial justice.
- 14. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the transactions complained of herein occurred in this District, and Defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

PARTIES

A. Plaintiff

15. Plaintiff Elizabeth A. Recupero is, and was at relevant times, a shareholder of

Osiris. Plaintiff purchased her Osiris shares on February 21, 2014 and still holds her shares as of the date of the filing of this derivative Complaint, and plans to retain these shares throughout the duration of the litigation. Plaintiff will fairly and adequately represent the interests of the shareholders in enforcing the rights of the corporation. Plaintiff is a citizen of Massachusetts.

B. Nominal Defendant

16. *Nominal Defendant Osiris Therapeutics, Inc.* is a Maryland corporation with its principal executive offices located at 1715 Albert Einstein Dr., Columbia, Maryland, 21046.

C. Director Defendants

- 17. **Defendant Peter Friedli** ("Friedli") was one of the Company's co-founders and has served on the Board as a Director ("Board") from January 1996 to the present, aside from a brief period between February and June 2004. He currently serves as Chairman of the Board of Friedli Corporate Finance, Inc. ("FCF"), a Swiss venture capital firm at which Friedli serves as Principal, and which has been the primary source of financing for the Company throughout its lifetime. As evidenced by the Company's 2015 Definitive Proxy Statement, Friedli is the beneficial owner of 14,810,455 shares of Osiris stock, representing approximately 43% of the Company's outstanding stock with a value of over \$213 million. Upon information and belief, Friedli is a citizen of Switzerland.
- 18. **Defendant Jay M. Moyes** ("Moyes") has served on the Board since 2006 and is currently as Chairman of the Audit Committee, a member of the Nominating Committee, and a member of the Compensation Committee. Upon information and belief, Moyes is a citizen of Utah or Nevada.
- 19. **Defendant Yves Huwyler** ("Huwyler") has served on the Board since June 10, 2015 and is currently as a member of the Audit Committee, Chair of the Nominating Committee, and

Chair of the Compensation Committee. Huwyler was a Director at Friedli Corporate Finance until 2012. Upon information and belief, Huwyler is a citizen of Switzerland.

- 20. **Defendant Thomas M. Brandt** ("Brandt") has recently been elected to the Board in 2016. Brandt is a member of the Audit Committee. Upon information and belief, Brandt is a citizen of Maryland.
- 21. According to the Company website, there are only four members of the Board. *See* http://investor.osiris.com/directors.cfm. (last visited on February 7, 2017).

Non-Parties

- 22. Lode Debrabandere ("Debrabandere") served as the Company's President and CEO from December 2011 and as a Director from January 2014 until February 3, 2016 when his resignation from all three positions was announced.
- 23. Dwayne Montgomery ("Montgomery") served as the Company's Chief Business Officer from September 2015 to February 3, 7016 when he was appointed Interim CEO upon Debrabandere's departure. On March 3, 2016, he was appointed President and CEO and elected to the Board. On June 10, 2016, Montgomery's resignation as President, CEO, and Director was announced and was replaced by David A. Dresner ("Dresner") in his capacities as President and CEO.

CODE OF BUSINESS CONDUCT AND ETHICS

- 24. As members of Osiris' Board, Defendants were held to the highest standards of honesty and integrity and charged with overseeing the Company's business practices and policies, and assuring the integrity of its financial and business records.
- 25. The conduct of Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Osiris, the absence of good faith on their

part, and a reckless disregard for their duties to the Company and its investors that Defendants were aware posed a risk of serious injury to the Company.

THE COMPANY'S AUDIT COMMITTEE CHARTER

- 26. The Audit Committee assists the Board in fulfilling its responsibility for oversight of the quality and integrity of the accounting, audited and reporting practices of the Company and such other duties as directed by the Board. The Audit Committee's role includes a particular focus on the qualitative aspects of financial reporting to the Company's stockholders as well as the Company's internal control over such financial reporting, the Company's processes to manage business and financial risk and compliance with significant applicable legal, ethical and regulatory requirements. The Audit Committee is responsible for providing an avenue of communication among the independent auditors, management and the Board. The Audit Committee is directly responsible for the appointment, compensation, and oversight of the public accounting firm engaged for the purpose of preparing or issuing an audit report or related work. In addition, the Audit Committee is responsible for pre-approving all permissible non-audit services and for pre-approving all audit, review and attest engagements that are provided to the Company by its independent auditors.
- 27. The Audit Committee's Charter states that the Audit Committee's responsibilities are as follows:

Review and reassess the adequacy of [the] Charter at least annually. Submit the Charter to the Board for approval and have the Charter published at least every three years or as otherwise required by SEC Rules and the Listing Standards.

Review the Company's annual audited financial statements and management's discussion and analysis of financial condition and results of operations ("MD&A") prior to filing or distribution. The review should include discussion with management and the independent auditors of significant issues regarding the quality of the Company's accounting

policies and principles as applied in its financial reporting, including any changes in the Company's selection or application of accounting principles, practices, judgments, audit adjustments and significant estimates, accruals and reserves. Based on that review, the Committee shall make a recommendation to the Board as to whether or not the financial statements should be included in the Annual Report on Form 10-K.

Review and discuss with management and the independent auditors the Company's internal controls report and the independent auditor's attestation report prior to the filing of the Company's Annual Report on Form 10-K.

Review earnings releases with the Chief Financial Officer and the independent auditors prior to dissemination, and, in particular, discuss non-GAAP information guidance.

Prior to filing periodic reports with the SEC, review and monitor with the Chief Financial Officer and the independent auditors:

- Management's disclosures to the Committee under Section 302 of the Sarbanes-Oxley Act of 2002;
- The contents of the officer's certifications required by applicable law to be included with or in the Company's periodic reports filed with the SEC and establish a procedure for being notified if such certifications are not included for any reason;
- Financial information and MD&A;
- Significant issues and transactions; and
- Significant changes in operations.

Review with the Chief Financial Officer any significant changes to generally accepted accounting principles.

Periodically review with the Chief Financial Officer and the independent auditors:

- The adequacy of the Company's internal controls, including information technology controls and security.
- The adequacy of disclosure controls and procedures.
- Any significant issues or findings and recommendations of the independent auditors together with management's responses thereto.
- The adequacy of disclosures about changes in internal controls over financial reporting.

Periodically inquire with the Chief Financial Officer and the independent auditors about significant risks and assess the steps management has taken to mitigate such risks.

Provide active oversight over management's anti-fraud program.

Approve all related party transactions, as defined by applicable Listing Standards, to which the Company is a party.

DUTIES OF DEFENDANTS

- 28. By reason of their positions as officers and/or directors of the Company, and because of their ability to control the business and corporate affairs of Osiris, Defendants owed Osiris and its investors the fiduciary obligations of trust, loyalty, and good faith. The obligations required Defendants to use their utmost abilities to control and manage Osiris in an honest and lawful manner. Defendants were and are required to act in furtherance of the best interests of Osiris and its investors.
- 29. Each director of the Company owes to Osiris and its investors the fiduciary duty to exercise loyalty, good faith, and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets. In addition, as officers and/or directors of a publicly held company, Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company's operations, finances, and financial condition, as well as present and future business prospects, so that the market price of the Company's stock would be based on truthful and accurate information.
- 30. To discharge their duties, the officers and directors of Osiris were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the affairs of the Company. By virtue of such duties, the officers and directors of Osiris were required to, among other things:

- (a) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;
- (b) conduct the affairs of the Company in an efficient, businesslike manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;
- (c) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's business prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;
- (d) remain informed as to how Osiris conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiries in connection therewith, take steps to correct such conditions or practices, and make such disclosures as necessary to comply with federal and state securities laws;
- (e) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable federal, state and local laws, and rules and regulations; and
- (f) ensure that all decisions were the product of independent business judgment and not the result of outside influences or entrenchment motives.
- 31. Each defendant, by virtue of his position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith, and the exercise of due

care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Osiris, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that Defendants were aware, or should have been aware, posed a risk of serious injury to the Company.

SUBSTANTIVE ALLEGATIONS

A. Background

- 32. Osiris researches and develops biosurgery solutions, focusing on "products for wound care, cartilage repair, and orthopedics, to harness the ability of cells and novel constructs to promote the body's natural healing."
- 33. Osiris was incorporated in 1992 and is based in Columbia, Maryland. Its shares trade on the NASDAQ under the ticker symbol "OSIR".

MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE RELEVANT PERIOD

- 34. On May 12, 2014, the Company issued a press release entitled *Osiris Reports First Quarter 2014 Results: Revenue Up 25% and Gross Margin improved from 73% to 78%*. This press release set forth the following "Highlights and Recent Developments":
 - Increased product revenue for the quarter to \$10.1 million -- a 146% increase over the first quarter 2013 and 25% from previous quarter.
 - Improved gross margin from 73% in previous quarter to 78% in the first quarter of 2014 gross profit increased 169% over the first quarter of 2013 and 32% over the previous quarter.
 - Obtained Medicare coverage in 9 states representing 18% of Medicare-insured lives.
 - Expanded commercially, adding 70 experienced wound care

professionals to the organization

- Presented Grafix® pharmacoeconomic and scientific studies at Symposium for Advanced Wound Care demonstrating statistically significant economic benefits of wound closure and showing a quantitative comparison of wound relevant pharmacological parameters between cryopreserved and non-cryopreserved human amnion membranes.
- Featured at the 2014 American Academy of Orthopaedic Surgeons Annual Meeting, a Cartiform® study confirming preservation of three-dimensional biologic architecture found in native articular cartilage.
- Strengthened management team promoting Frank D. Czworka, Jr., to Vice President and General Manager of Wound Care, appointing Therésa K. Dixon, to General Manager, Market Access and Reimbursement, and Dwayne Montgomery to General manager, Orthopedics and Sports Medicine.
- Engaged Svrithcs Chairman Emeritus Hansjorg Wyss to serve as a strategic advisor to the company
- Received \$15 million cash payment from Mesoblast related to Prochymal the third milestone of the Purchase Agreement worth up to \$100 million plus royalties.
- Reported loss from continuing operations of \$0.6 million for first quarter 2014, ending the quarter with \$91.3 million of total assets.
- 35. The press release also stated: "Research and development expenses for the first quarter of 2014 were \$0.7 million, decreased from the \$1.0 million incurred in the first quarter of 2013. As a result of our increased commercial activity, our selling, general and administrative expenses were \$7.2 million for the first quarter of 2014, compared to \$2.4 million for the same period of the prior year."
- 36. Debrabandere also stated: "Our focus on execution has driven this strong start to 2014. Now, along with the addition of key leadership, we are poised to carry this momentum forward as we continue to grow every facet of our business."
 - 37. On May 12, 2014, the Company filed a Form 10-Q with the SEC for the first quarter

of 2014 that restated the financial results expressed in the May 12, 2014 press release and assured investors that "[t]here [had] not been any changes in [the Company's] internal control over financial reporting that occurred during the quarter ended March 31, 2014 that [had] materially affected, or [was] reasonably likely to materially affect, [the Company's] internal control over financial reporting."

- 38. The Company's May 12, 2014 Form 10-Q also disclosed: "During the first fiscal quarters of fiscal 2014 and 2013, revenues from one of the distributors of our Biosurgery products, Stability Biologics, comprised approximately 58% and 64%, respectively, of our total Biosurgery product revenues."
- 39. On August 7, 2014, the Company issued a press release entitled *Osiris Therapeutics*Announces Second Quarter 2014 Financial Results: Revenue Up 32% Over Previous Quarter.

 This press release set forth the following "Highlights and Recent Developments":
 - Increased product revenue for the quarter to \$13.3 million a 151% increase over Q2 2013 and a 32% increase over previous quarter.
 - Held gross margin steady at 78% gross profit increased 172% over Q2 2013 and 32% over previous quarter.
 - Completed the quarter with a loss from continuing operations (excl. non-cash items) of \$66,000.
 - Obtained Medicare coverage in 10 states, representing 27% of Medicare-insured lives. Published manuscript in the International Wound Journal from Osiris' multi-center (n=20), randomized, controlled clinical trial, Protocol 302, which demonstrated overwhelming efficacy of Grafix® compared to control in the closure of diabetic foot ulcers over 12 weeks (62% vs. 21.3%, p=0.0001, n=97).
 - Agreed on path forward with FDA to complete a Biologics License Application for Grafix in order to obtain additional claims and indications.
 - Added several new sizes to the Grafix product lines, giving health care providers the ability to optimally match Grafix to the wound size, reduce

overall treatment costs, and eliminate concerns regarding product waste. Grafix. is well-positioned to remain a cost effective option within the Centers for Medicare & Medicaid Services bundled payment system.

- 40. The press release also stated: "Research and development expenses for the second quarter of 2014 were 1.1 million, an increase from \$0.7 million in the first quarter of this year. As a result of our increased commercial activity, our selling, general and administrative expenses were \$9.3 million for the second quarter of 2014, compared to \$54.2 million for the same period of the prior year."
- 41. Debrabandere stated in the press release: "It is very encouraging that the quarter-over-quarter revenue growth of 32% was largely driven by our new wound care sales team . . . Revenue growth and bottom line improvement were impressive while we continue to invest and differentiate our products scientifically, clinically and through regulatory strategies."
- 42. On August 11, 2014, the Company filed a Form 10-Q with the SEC for the second quarter of 2014 that discussed the financial results expressed in the August 7, 2014 press release and assured investors that "[t]here [had] not been any changes in [the Company's] internal control over financial reporting that occurred during the quarter ended June 30, 2014 that [had] materially affected, or [was] reasonably likely to materially affect [the Company's] internal control over financial reporting."
- 43. On November 7, 2014, the Company issued a press release entitled *Osiris* Therapeutics Announces Third Quarter 2014 Financial Results: Revenue up 29% and Company Turned Profitable. This press release set forth the following "highlights and Recent Developments":
 - Increased product revenue for the quarter to \$17.2 million a 29% increase over previous quarter and 150% increase over the same period last year. Held gross margin steady at 78% for the first three quarters of fiscal 2014.

- Completed the quarter with income from continued operations of \$710,000 or \$0.02 per share.
- Increased Medicare coverage from 10 to 29 states, representing an increase from 27% to 72% of Medicare-insured lives compared to previous quarter.
- Entered into an exclusive distribution partnership for our cartilage regenerating product Cartiform® with Arthrex Inc., the leader in sports medicine.
- Obtained final letter from FDA confirming the resolution of the issues of the Untitled Letter of September 2013 and submitted the confirmatory Phase III clinical trial protocol for chronic wounds to medical reviewer. Osiris is seeking BLA approval for our amnion/chorion products for additional claims and indications.
- Prochymal® submitted to Japanese Health Authorities by our partner Mesoblast, seeking approval for pediatric and adult Graft-versus-Host Disease.
- 44. The press release also noted: "Research and development expenses for the third quarter of 2014 were \$1.2 million, an increase from the \$0.9 million incurred in the same period of the prior year. As a result of our increased commercial activity, our selling, general and administrative expenses were \$10.9 million for the third quarter of 2014, compared to \$4.0 million for the same period of the prior year."
- 45. Debrabandere also stated in the press release: "This quarter represents a turning point for Osiris Our wound care business continues to drive revenue growth supported by the expansion of the sales force, the significant increase in the number of approvals for Medicare reimbursement and the positive scientific, clinical and pharmaco-economic data of Grafix®."
- 46. On November 10, 2014, the Company filed a Form 10-Q with the SEC for the third quarter of 2014 that discussed the financial results expressed in the November 7, 2014 press release and assured investors that "[t]here [had] not been any changes in the [Company's] internal control over financial reporting that occurred during the quarter ended September 30, 2014 that

[had] a materially affected, or [was] reasonably likely to materially affect [the Company's] internal control over financial reporting."

- 47. On March 5, 2015, the Company issued a press release entitled *Osiris Therapeutics* Fourth Quarter and Full Year 2014 Financial Results: For the Full Year, Revenue Increased 146% and Company Reports Record Revenue in Fourth Quarter. This press release set forth the "Full Year and Fourth Quarter Highlights":
 - Reported product revenue of \$59.9 million in 2014, up 146% from the prior year.
 - Increased gross profit from operations from \$17.7 to \$46.7 million, up 164% from the prior year. Gross margin improved from 73% to 78%.
 - Signed strategic commercial partnerships for the Orthopaedics unit, BIO4 TM with Stryker Corporation, and for the Sports Medicine unit, Cartiform® with Arthrex, Inc.
 - Improved Medicare reimbursement for Grafix® to over 70% of Medicare insured lives, compared to no reimbursement in 2013.
 - Strengthened the leadership team and made significant progress in transforming Osiris to a competitive commercial enterprise through the addition of 106 sales professionals and the creation of marketing, customer service, health policy and reimbursement departments.
 - Product revenue for the quarter rose to \$19.3 million, a 138% increase compared to fourth quarter 2013.
 - Completed the quarter with income from continuing operations of \$1.1 million, or \$0.03 per share, after recognizing income taxes of \$89,000.
 - Obtained final letter from FDA confirming the resolution of the issues of the Untitled Letter of September 2013. Osiris submitted an IND for our viable placental membrane for the treatment of chronic wounds and will conduct a confirmatory Phase 3 trial to seek BLA approval.
 - Prochymal® submitted to Japanese Health Authorities by our partner Mesoblast, seeking approval for pediatric and adult Graft-versus-Host Disease.

- 48. The press release also stated: "Research and development expenses for the fourth quarter of 2014 were \$3.9 million, an increase from the \$1.9 million incurred in the same period of the prior year. As a result of our increased commercial activity, our selling, general and administrative expenses were \$10.0 million for the fourth quarter of 2014, compared to \$4.1 million for the same period of the prior year."
- 49. Debrabandere also stated in the press release: "We continue to grow revenue, add commercial talent and expand our pipeline in our Orthopaedics, Sports Medicine and Wound Care units [...]. Our investments in wound care resulted in rapid revenue growth in both commercial and federal payor segments with wound care sales quadrupling compared to 2013. We are also looking forward to the launch of both BIO4 and Cartiform in collaboration with Stryker and Arthrex, respectively."
- 50. On March 20, 2015, the Company filed a Form 10-K with the SEC for the fiscal year ended December 30, 2014 that discussed the financial results expressed in the March 5, 2015 press release. The Form 10-K stated in relevant part:

Previously Reported Material Weakness. During the year ended December 31, 2014, we developed and implemented new control procedures to address a previously identified material weakness in our internal control over financial reporting. As of December 31, 2013, our management determined that our processes, procedures and controls related to financial reporting were not effective to ensure effective oversight of the work performed by, and the accuracy of financial information or professional conclusions provided by, third-party tax advisors, regarding components of the income tax provision calculation (specifically the allocation between continuing and discontinuing operations), given a one-time significant transaction of disposing of a business segment. We have taken steps to remediate the material weakness, including adherence to existing control procedures and implementation of enhanced controls related to review and oversight of complex transactions and infrequent events. Additionally, we engaged a new third party tax advisor to oversee and prepare the Company's tax provision and other related documents. We believe that these remediation efforts have improved our internal control over tax accounting, as well as our disclosure controls and procedures, and that the material weakness has been remediated at December 31, 2014.

- 51. The press releases and financial documents described above contained statements that were materially false and misleading, and/or failed to disclose the following relevant facts:

 (a) the Company's internal controls over financial reporting were ineffective and inadequate beginning at least as early as December 2014 and remained so despite Defendants' knowledge of the deficiencies (b) as a result of the deficiencies in its internal controls, the revenues that the Company reported from contracts with its distributors were materially inflated; and (3) the statements issued by Defendants regarding the Company's present performance and future outlook were materially false and misleading, and/or lacked a reasonable basis.
- 52. On May 8, 2015, the Company issued a press release entitled *Osiris Therapeutics*Announces First Quarter 2015 Financial Results. This press release set forth the following
 "Highlights and Recent Developments":
 - Increased product revenue for the quarter to \$21.0 million a 109% increase over Q1 2014.
 - Held gross margin remained consistent at 78%.
 - Completed the quarter with after-tax income from operations of \$1.4 million or \$0.04 per share.
 - Launched BIO4 TM in collaboration with Stryker at the American Academy of Orthopaedic Surgeons.
 - Increased coverage to 40 million Medicare lives, 21 million Medicaid lives and initiated commercial coverage for 37 million lives for Grafix®.
 - Ended the quarter with \$101.6 million of total assets.
- 53. The press release also stated: "Research and development expenses for the first quarter of 2015 were \$1.6 million, increased from the \$0.7 million incurred in the first quarter of 2014. As a result of our increased commercial activity, our selling, general and administrative expenses were \$12.8 million for the first quarter of 2015, compared to \$7.2 million for the same

period of the prior year."

- 54. Debrabandere also stated: "I am encouraged by the continued growth of our business, despite the changing market dynamics we experienced in the first quarter [...]. During this quarter, our business completed the transition from Ovation® to BIO4 and also successfully adjusted to the CMS bundled-payment system inclusion of Grafix. The wound care business continues to gain momentum, supported by the expansion of Medicare, Medicaid and commercial insurance coverage."
- 55. On May 11, 2015, the Company filed a Form 10-Q with the SEC for the first quarter of 2015 that discussed the financial results expressed in the May 8, 2015 press release and assured investors that "[t]here [had] not been any changes in [the Company's] internal control over financial reporting that occurred during the quarter ended March 31, 2015 that [had] materially affected, or [was] reasonably likely to materially affect, [the Company's] internal control over financial reporting."
- 56. The Form 10-Q filed on May 11, 2015 also contained the following statement regarding the Company's disclosure controls and procedures:

Evaluation of Disclosure Controls and Procedures. An evaluation of the effectiveness of the design and operation of our "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Quarterly Report on Form 10-Q was made under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (a) are effective to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is timely recorded, processed, summarized and reported and (b) include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

- 57. The Company's May 11, 2015 Form 10-Q also disclosed the following: "During the first fiscal quarters of fiscal 2015 and 2014, revenues from one of the distributors of our Biosurgery products, Stability Biologics, comprised approximately 13% and 15%, respectively, of our total Biosurgery product revenues." The Company's claim that revenues from Stability Biologics comprised approximately 15% of total Biosurgery revenues in the first fiscal quarter of 2014 directly contradicts the Company's earlier claim in its May 12, 2014 Form 10-Q for the first fiscal quarter of 2014, wherein it attributes approximately 58% of its total Biosurgery revenues to Stability Biologics.
- 58. The press release and the May 11, 2015 Form 10-Q described above contained statements that were materially false and misleading, and/or failed to disclose the following relevant facts: (a) the Company's internal controls over financial reporting were ineffective and inadequate beginning at least as early as December 2014 and remained so despite Defendants knowledge of the deficiencies; (b) as a result of the deficiencies in its internal controls, the revenues that Company reported from contracts with its distributors were inflated and inaccurate; and (c) the statements issued by Defendants regarding the Company's present performance and future outlook were materially false and misleading, and/or lacked a reasonable basis. Product revenues for Q1 2015, which the Company claimed to be \$21 million, were in fact only \$19.2 million, or 8.5% less than stated; income from continuing operations which the Company claimed to be \$1.4 million, were in fact only \$484,000, or 64.4% less.
- 59. On August 5, 2015, the Company issued a pass release entitled *Osiris Therapeutics*Announces Second Quarter 2015 Financial Results. This press release set forth the following
 "Highlights and Recent Developments":

- Increased product revenue for the quarter to \$23.7 million a 78% increase over Q2 2014 and a 13% increase over previous quarter.
- Increased coverage for Grafix® to 123 million lives, an increase of 25 million lives compared to the previous quarter.
- Published seven peer reviewed manuscripts, including data on a prospective study of Grafix in chronic venous ulcers.
- Initiated preparations for a Phase III confirmatory study in venous ulcers with the goal to prepare a supplemental BLA for that indication.
- Invested further in the expansion of the commercial infrastructure, including the addition of sales and marketing professionals and establishment of an internal hotline and insurance verification department.
- Completed the quarter with after-tax income from operations of \$1.2 million or \$0.03 per share and with \$103 million in total assets.
- 60. The press release also stated: "Research and development expenses for the second quarter of 2015 were \$2.3 million, increased from the \$1.1 million incurred in the second quarter of 2014. As a result of our increased commercial activity, our selling, general and administrative expenses were \$14.5 million for the second quarter of 2015, compared to \$9.4 million for the same period of the prior year."
- 61. Debrabandere also stated in the press release: "We remain laser focused on growing revenue and investing in our leading brands [...]. Despite the expiration of pass-through status for Grafix in early January, the wound care business continues to grow revenue by double-digits. The team has made tremendous progress in opening more accounts and increasing the number of patients treated with Grafix."
- 62. On August 10, 2015, the Company filed a Form 10-Q with the SEC for the second quarter of 2015 that discussed the financial results expressed in the August 5, 2015 press release and assured investors that "[t]here [had] not been any changes in [the Company's] internal controls over financial reporting that occurred during the quarter ended June 30, 2015 that [had] materially

affected, or [was] reasonably likely to materially affect [the Company's] internal controls over financial reporting."

63. The press release and Form 10-Q described above contained statements that were materially false and misleading and/or failed to disclose the following relevant facts: (a) the Company's internal controls over financial reporting for revenue recognition were ineffective and inadequate beginning at least as early as December 2014 leading to material misstatements of revenue and remained so despite Defendants knowledge of the deficiencies; (b) as a result of the deficiencies in its internal controls, the revenues that the Company reported from contracts with distributors were materially inflated; and (c) the statements issued by Defendants regarding the Company's present performance and future outlook were materially false and misleading, and/or lacked a reasonable basis. Product revenues for Q2 2015, which the Company claimed to be \$23.7 million, were in fact only \$22.7 million, or 4.0% less than stated income from continuing operations, which the Company claimed to be \$1.2 million, were in fact only \$795,000, or 31.7% less.

THE TRUTH EMERGES

64. On November 16, 2015, the Company disclosed that it has "determined to correct the revenue recognition for three contracts which will result in a decrease in product revenues of \$1.8 million in the first quarter of 2015, a decrease in product revenue of \$1.0 million in the second quarter, an increase in product revenues of \$0.8 million in the third quarter of 2015 and a decrease in product revenues of \$1.1 million in 2014." Thus, three restatements were made related to distributor relationships, which completely removed about \$3.1 million of sales and shifted about \$3.9 million of sales between quarters. As a result of these false accounting statements, the Company missed its revenue targets in three of the last four quarters.

- 65. The November 16, 2015 Form 10-Q also included the following statement: "On occasion, customers purchase product and request that the Company store the purchased product in segregated freezers at the Company's facility. In those cases, title passes to the customer and the customer accepts all risks associated with the purchased product. Customers may request this service of the Company in instances where they want to ensure that supply of product is available to them and they do not have the capability to store the product themselves in special freezers at 80 degrees Celsius."
- 66. Such "bill and hold" arrangements are permitted by the SEC only rarely. According to guidance set forth on the SEC website:

The Commission has set forth criteria ["Bill and Hold Criteria"] to be met in order to recognize revenue when delivery has not occurred. These include:

- 1. The risks of ownership must have passed to the buyer;
- 2. The customer must have made a fixed commitment to purchase the goods, preferably in written documentation;
- 3. The buyer, not the seller, must request that the transaction be on a bill and hold basis. The buyer must have a substantial business purpose for ordering the goods on a bill and hold;
- 4. There must be a fixed schedule for delivery of the goods. The date for delivery must be reasonable and must be consistent with the buyer's business purpose (e.g., storage periods are customary in the industry);
- 5. The seller must not have retained any specific performance obligations such that the earning process not complete;
- 6. The ordered goods must have been segregated from the seller's inventory and not be subject to being used to fill other orders; and
- 7. The equipment [product] must be complete and ready for shipment.
- 67. While the Company's recognition of its bill and hold revenues seems to satisfy some of the Bill and Hold Criteria, its disclosure in the November 16, 2015 Form 10-Q

demonstrates that other Bill and Hold Criteria were disregarded. The Company's stated reason that a buyer would request a bill and hold arrangement was that "supply of the product is available to them" in the future. This reason shows that there was, in fact, no fixed schedule for delivery of the Company's goods as stipulated by the fourth Bill and Hold Criterion. In addition, the requirement that the Company store the held product in "special freezers at 80 degrees Celsius" proves a specific performance obligation such that the Company's "earning process is not complete" in direct violation of the fifth Bill and hold Criterion. The Company's disregard for these two Bill and Hold Criteria in its revenue recognition shows a conscious attempt to incorrectly recognize revenues for product which, according to SEC regulations, it had not sold.

- 68. The Bill and Hold Criteria were essential components of a business that attempted to book legitimate Bill and Hold sales, rarely permitted by the SEC. Defendants' alleged ignorance of the Bill and Hold Criteria is gross negligence. Their knowledge of the Bill and Hold Criteria demonstrates that Defendants committed fraud.
- 69. On November 20, 2015, the Company filed a Form 8-K with the SEC disclosing that the Company's internal controls over financial reporting were inadequate and restating the inaccuracy of the Company's 10-Q Forms for the first and second quarters of 2015 and its Form 10-K for the 2014 fiscal year. The Form 8-K stated:

Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

(a) Osiris Therapeutics, Inc. (the "Company") previously disclosed in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 ("Third Quarter 2015 Form 10-Q") that it had undertaken a review of the timing of revenue recognition under contracts with its distributors. As a result of this review, the Company determined to correct the revenue recognition for three contracts, which resulted in a decrease in product revenues of \$1.8 million in the first quarter of 2015, a decrease in product revenues of \$1.0 million in the second quarter of 2015, an increase in product revenues of \$0.8 million in the third quarter of 2015 and a decrease in product revenues of \$1.1 million in 2014. Each of these transactions

are net of applicable cost of sales. These corrections were reflected in the Third Quarter 2015 Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 16, 2015.

Restatements of Interim Quarterly Periods Ending March 31, 2015 and June 30, 2015

While the impact of these modifications to the Company's revenue recognition practices for certain distribution contracts is immaterial to its annual financial statements for the year ended December 31, 2014, the impact on the quarterly periods ending March 31, 2015 and June 30, 2015 is material. As a result, the Company will restate its previously issued interim financial statements for first quarter and second quarter of 2015 through the filing of amended Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015. These amended quarterly reports will be filed with the SEC as soon as administratively possible. On November 16 2015, management of the Company, in consultation with the Audit Committee of the Board of Directors and the Company's independent registered public accounting firm, concluded that investors should no longer rely on the Company's previously issued financial statements for the quarterly periods ended March 31, 2015 and June 30, 2015 and on any prior earnings releases or other communications relating to such periods.

Background

Under US GAAP, revenue is generally recognized when persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectability is probable. The Company previously recognized revenue under these three distributor contracts which was reflected in the Company's audited financial statements in its Annual Report on Form 10-K for the year ended December 31, 2014 and its unaudited financial statements in its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015.

Upon subsequent review in connection with the Company's review of its third quarter 2015 financial statements, the Company determined, in consultation with its independent registered public accounting firm, that the transactions did not meet certain conditions for revenue recognition in the fourth quarter of 2014, and the first and second quarters of 2015. For one transaction in the fourth quarter of 2014, the Company determined that the persuasive evidence of an arrangement was not met until January 2015 and the price was not fixed and determinable in the quarter that the revenues were previously recognized, nor was it determined to be fixed and determinable as of the first quarter of 2015. As a result, the Company is required to account for the contract with this distributor under the cash basis of accounting, which means that revenues are recognized when cash receipts are actually received. Correcting this revenue recognition error in one contract will result in an increase in product revenues of approximately \$0.8 million, net of cost of sales, in the third quarter of 2015 and a decrease in product revenues of approximately \$1.1 million,

net of cost of sales, in the fourth quarter of 2014. The approximate \$0.3 million difference between the \$0.8 million increase in product revenues for the third quarter of 2015 and the \$1.1 million decrease in product revenues in 2014 will not be included as an accounts receivable as of the end of the third quarter of 2015, but will be recorded as product revenue in future periods when and if such amounts are actually received.

The Company also sold product to the same distributor during the first quarter of 2015. The Company is also recognizing this sale on the cash basis of accounting. Correcting this revenue recognition error will result in a decrease in product revenues of approximately \$0.8 million, net of cost of sales, in the first quarter of 2015. The \$0.8 million of accounts receivable will not be included as an accounts receivable as of the end of the first quarter of 2015, but will be recorded as product revenue in future periods when and if such amounts are actually received.

Also during the first quarter of 2015, the Company recognized a \$0.7 million sale, net of cost of sales, to a distributor that ordered products for sale outside of the United States. During its review of all distributor contracts undertaken during the third quarter 2015 period close process, the Company also determined that revenue recognition of this first quarter 2015 transaction is appropriate in a future period when the distributor achieves full regulatory approval in the country where they will be selling the product. This determination was made because the distributor has the right to return the product if regulatory approval is not achieved.

During the third quarter of 2015, the Company received final pricing information from another distributor which showed the average price for product sales during the year. This distributor first sold product for the Company during the first quarter of 2015. The distributor has the right to sell the product at any price, as long as it is sold above a contractually set minimum price. The impact of this price adjustment was \$0.3 million revenue reduction during the first quarter 2015 and \$1.0 million reduction during the second quarter 2015. The revenue adjustment was offset by a reduction in costs of goods sold, commissions and fees related to that revenue. This adjustment was preliminarily recorded during the third quarter of 2015, but a determination was made to adjust previous quarters to reflect the proper impact of the adjustment to previously reported periods. The Company believes that this revenue was fixed and determinable at the time of revenue recognition during the first and second quarters of 2015 given that the contract sets an agreed-upon minimum price.

The following tables present the effects of the corrections on the Company's financial statements for the first and second quarters of 2015:

Case 1:17-cv-00381-JFM Document 1 Filed 02/09/17 Page 27 of 45

		As Previously Reported					
		_		Q1 2015		Q2 2015	
Product revenues		\$	21,	003	\$	23,688	
Cost of product revenue			4,	609		5,142	
Gross profit			16,	394		18,540	
Selling, general, and administrative expenses			12,911			14,526	
Income taxes expense			612			367	
Income (loss) from continuing operations	1		1,377			1,164	
Net income (loss)				377		1,164	
Diluted income (loss) per share			\$ 0.04			0.03	
Trade accounts receivable, net		\$	32,	022	\$	38,598	
Inventory	\$		11,939	\$	13	3,348	
Total liabilities	\$		15,128	\$	14,185		
Total stockholders' equity	\$		86,484	\$	88	3,822	
	_	Adjustments					
	<u> </u>	Q1	2015		Q2 201	5	
Product revenues	\$		(1,788)	\$		(957)	
Cost of product revenue			(319)			_	
Gross profit			(1,469) (957)				
Selling, general, and administrative expenses			(175) (497)				
Income taxes expense			(402) (91)				
Income (loss) from continuing operations			(892) (369)				
Net income (loss)			(892) (369)				
Diluted income (loss) per share	\$		(0.02)	\$	(0.01)		
Trade accounts receivable, net	\$		(2,860)			3,817)	
Inventory	\$		555	\$	(-	555	
Total liabilities					/1		
	\$		(630)	\$,	1,350)	
Total stockholders' equity	\$		(2,305)	\$	(:	3,262)	

		Restated					
	<u> </u>	Q1 2015	92	Q2 2015			
Product revenues	\$	19,215	\$	22,731			
Cost of product revenue		4,290		5,142			
Gross profit		14,925		17,589			
Selling, general, and administrative expenses		12,736		14,029			
Income taxes expense		210		276			
Income (loss) from continuing operations		485		795			
Net income (loss)		485		795			
Diluted income (loss) per share	\$	0.02	\$	0.02			
Trade accounts receivable, net	\$	29,162	\$	34,781			
Inventory	\$	12,494	\$	13,903			
Total liabilities	\$	14,498	\$	12,835			
Total stockholders' equity	\$	84,179	\$	85,560			
		Percentage Change					
		21 2015	(Q2 2015			
Product revenues		(8.51)%	0)	(4.04)%			
Cost of product revenue		(6.92)%		0.00%			
Gross profit		(8.96)%	ė.	(5.16)%			
Selling, general, and administrative expenses		(1.36)%	0	(3.42)%			
Income taxes expense		(65.69)%	i,	(24.80)%			
Income (loss) from continuing operations		(64.78)%	ř	(31.70)%			
Net income (loss)		(64.78)%	0;	(31.70)%			
Diluted income (loss) per share		(50.00)%	i,	(33.33)%			
Trade accounts receivable, net		(8.93)%	į.	(9.89)%			
Inventory		4.65%		4.16%			
Total liabilities		(4.16)%	į.	(9.52)%			
Total stockholders' equity		(2.67)%		(3.67)%			

The preliminary revisions set forth in the table above are based on currently available information and are subject to change during the course of the Company's process to restate prior quarterly financial statements. Until the process is complete, additional information may become available that could cause the Company's preliminary revisions to change.

Controls and Procedures

As previously disclosed in the Company's Third Quarter Form 10-Q, due to the material weakness in internal control over financial reporting described below, our management, including our Chief Executive Officer and Chief Financial Officer, re-evaluated its conclusions regarding our disclosure controls and procedures and concluded that our disclosure controls and procedures were not effective as of December 31, 2014, March 31, 2015, and June 30, 2015 solely because of the material weakness that existed at that time.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Management identified the following control deficiency that constituted a material weakness in our internal control over financing reporting that existed as of December 31, 2014, March 31, 2015, and June 30, 2015:

The Company did not design and maintain controls to ensure that (1) adequate written documentation existed for contracts with distributors in order to ensure that persuasive evidence of the contractual arrangement existed and the terms were fixed and determinable with respect to revenue recognition and (2) adequate analysis and documentation existed for new distributor contracts to ensure timely and accurate recording of revenue in accordance with GAAP.

Management has concluded that this material weakness, if un-remediated, could have, in future reporting periods, resulted in a material misstatement to the Company's annual or interim consolidated financial statements that would not have been prevented or detected by its internal controls. Accordingly, management has determined that this control deficiency constituted a material weakness. Management's report on internal controls over financial reporting for the year ended December 31, 2014 should no longer be relied upon. Additionally, the opinion of our independent registered public accounting firm on the effectiveness of the Company's internal controls over financial reporting as of December 31, 2014 should no longer be relied upon.

The Company's management is implementing certain enhancements and remedial measures to its internal control over financial reporting to specifically ensure that adequate written documentation and related controls exist for proper accounting of distributor contracts. They will continue to monitor the effectiveness of these processes, procedures and controls and will make any further changes deemed appropriate.

- 70. In the fiscal quarter of 2015, the Company reported product revenues of \$21 million when in fact they were only \$19.2 million (\$1.8million or 8.51% less); gross profits of \$16.4 million when in fact they were only \$14.93 million (\$1.47 million or 8.96% less); diluted income per share of \$0.04 when in fact it was only \$0.02, or 50.00% less; net trade accounts receivable of \$32 million when in fact they were only \$29.16 million (\$2.86 million or 8.93% less), and total stockholders' equity of \$86.48 million when in fact it was only \$84.18 million (\$2.3 million or 2.67% less).
- 71. In the second fiscal quarter of 2015, the Company reported product revenues \$23.7 million when in fact they were only \$22.7 million (\$957,000 or 4.04% less); gross profits of \$18.55 million when in fact they were only \$17.6 million (\$957,000 or 5.16% less); diluted income per

share of \$0.03 when in fact it was only \$0.02, or 33.33% less; net trade accounts receivable or \$38.6 million when in fact they were only \$34.78 (\$3.82 million or 9.89% less); and total stockholders' equity of \$88.82 million when in fact it was only \$85.56 million (\$3.26 million or 3.67% less).

- 72. On December 14, 2015, the Company received written notice of BDO's resignation, effective the same day, as its independent public accounting firm. It was announced that BDO "advised that their opinion on the effectiveness of the Company's interim controls over financial reporting as of December 31, 2014, should no longer be relied upon due management's identification of a material weakness in internal controls over financial reporting related to the timing of revenue recognition under certain distribution contracts."
- 73. On February 1, 2016, Debrabandere -- who served as the Company's President, CEO, and Board Director -- resigned from the Company.
- 74. On March 15, 2016, the Company announced that it had received subpoena from the SEC, which is conducting a non-public investigation relating to the Company's historic accounting practices.
- 75. On March 17, 2016, the Company received a deficiency notice from NASDAQ informing the Company that it had not timely filed its annual report on Form 10-K for the 2015 fiscal year and that the Company would be delisted from the stock exchange should it fail to submit a plan to regain compliance within the following 60 days,
- 76. On May 12, 2016, the Company received another notice from NASDAQ informing the Company that it had not timely filed its quarterly report on Form 10-Q for the first fiscal quarter of 2016 and that this represented an additional basis for non-compliance with NASDAQ listing requirements.

- 77. On May 24, 2016, NASDAQ granted the Company an exemption to the NASDAQ Listing Rule, extending the deadline for the delinquent documents filing to September 12, 2016.
- 78. On May 27, 2016, the Company disclosed in a regulatory filing that it is the subject of a criminal investigation by the U.S. Attorney's Office for the Southern District of New York, The Company said it believes the investigation is regarding the same matters as the SEC's "non-public investigation" disclosed in March into its accounting practices.
- 79. On August 12, 2016, the Company received a letter from the NASDAQ noting that the Company had not filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 with the SEC by its due date, in compliance with NASDAQ Listing Rule 5250(c)(1), which requires that NASDAQ-listed companies file their periodic financial reports with the SEC on a timely basis.
- 80. On September 16, 2016, the Company received a letter from the Listing Qualifications Department of the NASDAQ, stating that unless the Company requests a hearing before a NASDAQ Listing Qualifications Panel by September 21, 2016, the Company's common stock would be subject to delisting based upon the Company's current non-compliance with NASDAQ Listing Rule 5250(c)(1) as a result of certain delinquent SEC reports. On September 21, 2016, the Company requested an appeal of the NASDAQ Staff determination, and also requested a further stay of delisting.
- 81. On October 6, 2016, the Company received a letter from NASDAQ's Office of General Counsel stating that a NASDAQ Hearings Panel had granted the Company's request for a stay of the delisting of the Company's common stock until such time as the NASDAQ Hearings Panel makes a decision on the merits following a hearing, which hearing has been scheduled for November 10, 2016. The letter further stated that the Company's common stock will continue to

trade on the NASDAQ Stock Market pending the November 10, 2016 hearing and the issuance of a final decision by the NASDAQ Hearings Panel thereafter.

- 82. On November 15, 2016, the Company received a letter from the NASDAQ noting that the Company had not filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 with the SEC by its due date, in compliance with NASDAQ Listing Rule 5250(c)(1), which requires that NASDAQ-listed companies file their periodic financial reports with the SEC on a timely basis.
- 83. On December 1, 2016, the Company received a decision letter from NASDAQ's Office of General Counsel stating that the Hearings Panel has granted the Company's request and, accordingly, the Company's common stock will continue to trade on the NASDAQ Stock Market provided that the Company becomes current in its periodic filings with the SEC on or before March 10, 2017. The letter stated that March 10, 2017 represents the full extent of the Hearing Panel's discretion to grant continued listing while the Company is non-compliant.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

- 84. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties and gross mismanagement by Defendants.
- 85. Plaintiff will adequately and fairly represent the interests of the Company and its shareholders in enforcing and prosecuting its rights and has retained counsel competent and experienced in derivative litigation.
- 86. Plaintiff is a current owner of Osiris stock and has continuously been an owner of Osiris stock during all times relevant to Defendants' illegal and wrongful course of conduct alleged herein. Plaintiff understands his obligation to hold stock throughout the duration of this action and

are prepared to do so.

- 87. The Board consists of Defendants Friedli, Moyes, Huwyler, and Brandt. Because of the facts set forth throughout this Complaint, demand on the Board to institute this action is not necessary because such a demand would have been a futile and useless act.
- 88. The Board is currently comprised of four (5) members Friedli, Moyes, Huwyler and Brandt. Thus, Plaintiff is required to show that a majority of Defendants, *i.e.*, two (2), cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action.
- 89. Defendants Friedli, Moyes and Huwyler face a substantial likelihood of liability in this action because they caused the Company to issue false and misleading statements concerning its future prospects. Because of their advisory, executive, managerial, and directorial positions with the Company, Defendants Friedli, Moyes and Huwyler had knowledge of material non-public information regarding the Company and was directly involved in the operations of the Company at the highest levels.
- 90. Defendants Friedli, Moyes and Huwyler either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.
- 91. Defendants Friedli, Moyes and Huwyler cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. For the reasons that follow, and for reasons detailed elsewhere in this complaint, Plaintiff has not made (and should be excused from making) a pre-filing demand on the Board to initiate this action because making a demand would be a futile and useless act.
 - 92. Defendants Friedli, Moyes and Huwyler approved and/or permitted the wrongs

alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein, and are therefore not disinterested parties.

- 93. Defendants Friedli, Moyes and Huwyler authorized and/or permitted the false statements to be disseminated directly to the public and made available and distributed to shareholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.
- 94. Because of their participation in the gross dereliction of fiduciary duties, and breaches of the duties of due care, good faith, and loyalty, Defendants Friedli, Moyes and Huwyler are unable to comply with their fiduciary duties and prosecute this action. Each of them is in a position of irreconcilable conflict of interest in terms of the prosecution of this action.
- 95. Additionally, each of the Defendants received payments, benefits, stock options, and other emoluments by virtue of their membership on the Board and their control of the Company.

THE DIRECTOR DEFENDANTS ARE NOT INDEPENDENT OR DISINTERESTED

Defendant Friedli

- 96. Friedli is not disinterested or independent, and therefore, is incapable of considering demand because Friedli owns 14,810,455 shares of the Company stock or 43.1% of all the outstanding shares.
- 97. During the third quarter of fiscal 2011, the Company entered into a contract research agreement with Prolexys Pharmaceuticals, Inc. under which the Company is conducting for Prolexys an early stage clinical trial investigating a novel compound as a product candidate for

cancer therapeutics. The contract was filed as an exhibit to and discussed in a Current Report on Form 8-K filed by the Company with the SEC primarily because of the related nature of the management and ownership of Prolexys with the Company and the Company's management and with certain of significant stockholders of the Company.

98. Prolexys is 35.7% owned by BIH SA, which owns 7.7% of the Company's outstanding common stock; 24.3% owned by Friedli; and 13.8% owned by Venturetec, Inc., which holds 11.9% of the Company common stock. Friedli is the President and an approximately 2% owner of Venturetec, Inc. Friedli has also recently reported the acquisition of a convertible bond that would entitle him, upon conversion, to acquire an additional approximately 19% interest in Venturetec, Inc. Huwyler owns less than 1% of Prolexys and serves on its Board.

Defendant Moyes

- 99. Moyes is the Chairman of the Audit Committee.
- 100. During the Relevant Period, Moyes served as the Chairman of the Audit Committee. Pursuant to the Company's Audit Committee Charter, the members of the Audit Committee are responsible for, *inter alia*, overseeing the accounting and financial reporting processes of the Company and the audits of the financial statements of the Company. Specifically, the members of the Audit Committee are required to: (i) review the type and presentation of information to be included in the Company's earnings press releases, as well as financial information and earnings guidance provided by the Company to analysts and rating agencies, (ii) review the adequacy and effectiveness of the Company's accounting and internal control policies and procedures on a regular basis, and (iii) review the adequacy of the Company's independent auditor. Moyes breached his fiduciary duties of due care, loyalty, and good faith, because the Audit Committee, *inter alia*, allowed or permitted false and misleading statements to be

disseminated in the Company's SEC filings and other disclosures and, otherwise, failed to ensure that adequate internal controls were in place regarding the serious accounting issues and deficiencies described above. Therefore, Moyes face a substantial likelihood of liability for his breach of fiduciary duties and any demand upon him is futile.

Defendant Huwyler

- 101. Huwyler is a member of the Audit Committee.
- 102. During the Relevant Period, Huwyler served as a member of the Audit Committee. Huwyler breached his fiduciary duties of due care, loyalty, and good faith, because the Audit Committee, *inter alia*, allowed or permitted false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise, failed to ensure that adequate internal controls were in place regarding the serious accounting issues and deficiencies described above. Therefore, Huwyler face a substantial likelihood of liability for his breach of fiduciary duties and any demand upon him is futile.

Defendant Brandt

- 103. Brandt is a member of the Audit Committee.
- 104. During the Relevant Period, Brandt served as a member of the Audit Committee. Brandt breached his fiduciary duties of due care, loyalty, and good faith, because the Audit Committee, *inter alia*, allowed or permitted false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise, failed to ensure that adequate internal controls were in place regarding the serious accounting issues and deficiencies described above. Therefore, Brandt face a substantial likelihood of liability for his breach of fiduciary duties and any demand upon him is futile.

FIRST CAUSE OF ACTION

Against All Defendants for Breach of Fiduciary Duties

- 105. Plaintiff incorporates by reference and re-alleges each and every allegation contained in Paragraphs 1-104 above, as though fully set forth herein.
- 106. Defendants owe the Company and its shareholders fiduciary obligations. By reason of their fiduciary relationships, Defendants owed and owe the Company and its shareholders the highest obligation of good faith, fair dealing, loyalty, and due care.
- 107. Defendants also owed the shareholders, including minority shareholders, a duty not to exercise Defendants' control to the disadvantage of such shareholders.
- 108. Defendants also owed the Company and the shareholders a duty to perform their duties (1) in good faith; (2) in a manner they reasonably believe to be in the best interest of the Company; and (3) with the care than an ordinary prudent person in a like position would use under similar circumstances.
- 109. Defendants violated and breached their fiduciary duties (a) of care, loyalty, reasonable inquiry, good faith, (b) to not exercise their control to the disadvantage of shareholders, including but not limited to minority shareholder, and (c) to comply with the duties set forth in Paragraph 107 of this Complaint.
- 110. The preparation and dissemination of inaccurate information and SEC filings alleged herein represent a failure by Defendants to assure the existence within the Company of appropriate and adequate internal financial controls and a reasonable information and reporting system necessary to assure the accuracy of the Company's financial reporting.
- 111. When put on notice of internal control problems, Defendants had a fiduciary duty to promptly take appropriate action to correct the misconduct and prevent its recurrence

- 112. Defendants willfully ignored obvious and pervasive problems with the Company's internal controls alleged herein and by deliberate and knowing indifference failed to make a good faith effort to correct the problems until it was far too late.
- 113. Defendants violated their fiduciary duties, including but not limited to their duties of care, loyalty, and good faith, as well as the other duties set forth in Paragraphs 106-108 of this Complaint, by causing or allowing the Company to disseminate to stockholders materially inaccurate information through, *inter alia*, SEC filings and other public statements and disclosures. These actions could not have been a good faith exercise of prudent business judgment.
- 114. Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, oversight, good faith, and supervision, as well as the other duties set forth in Paragraphs 106-108 of this Complaint. By virtue of their conduct alleged herein, Defendants engaged in intentional misconduct and knowing violations of their duties.
- 115. As a direct and proximate result of Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, Defendants are liable to the Company.
- 116. As a direct and proximate result of Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs associated with defending securities lawsuits, severe damage to the share price of the Company, resulting in an increased cost of capital, the waste of corporate assets, and reputational harm.

WHEREFORE, Plaintiff demands judgment as follows:

A. Determining that this action is a proper derivative action maintainable under law, and that demand is excused;

- B. Awarding, against all Defendants and in favor of the Company, the damages sustained by the Company as a result of Defendants' breaches of their fiduciary duties;
- C. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its investors from a recurrence of the damaging events described herein;
- D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
 - E. Granting such other and further relief as the Court deems just and proper.

SECOND CAUSE OF ACTION

Against All Defendants for Negligent Breach of Fiduciary Duty

- 117. Plaintiff incorporates by reference and re-alleges each and every allegation contained in Paragraphs 1-116 above, as though fully set forth herein.
- 118. Each of the Defendants is serving or has served as a director or an officer of the Company and as such owed to the Company the highest fiduciary duties of loyalty, good faith, candor, due care and full disclosure. Each of the Defendants had a duty to ensure that the Company disseminated accurate, truthful, and complete information to its shareholders and exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.
- 119. Each of the Defendants negligently breached their duties of loyalty, good faith, candor, due care and full disclosure by causing or allowing the Company to violate the law and disseminate to the Company shareholders materially misleading and inaccurate information through, *inter alia*, SEC filings and other public statements and disclosures as detailed herein. These actions could not have been a good faith exercise of prudent business judgment.

- 120. As a direct and proximate result of Defendants' negligent failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, Defendants are liable to the Company.
- 121. As a direct and proximate result of Defendants' negligent breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs associated with defending securities lawsuits, severe damage to the share price of the Company, resulting in an increased cost of capital, the waste of corporate assets, and reputational harm.

WHEREFORE, Plaintiff demands judgment as follows:

- A. Determining that this action is a proper derivative action maintainable under law, and that demand is excused;
- B. Awarding, against all Defendants and in favor of the Company, the damages sustained by the Company as a result of Defendants' breaches of their fiduciary duties;
- C. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its investors from a recurrence of the damaging events described herein;
- D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
 - E. Granting such other and further relief as the Court deems just and proper.

THIRD CAUSE OF ACTION

Against All Defendants for Constructive Fraud

122. Plaintiff incorporates by reference and re-alleges each and every allegation

contained in Paragraphs 1-121 above, as though fully set forth herein.

- 123. Defendants, by reason of their positions as a director and/or officer of the Company, controlled the business and activities of the Company and such owed to the Company the highest fiduciary duties of loyalty, good faith, candor, and due care.
- 124. Defendants' breaches of their fiduciary duties constitute constructive fraud because they breached their fiduciary duties through conduct which deceived.
- 125. Defendants' breaches of their fiduciary duties constitute constructive fraud because they breached their fiduciary duties through conduct which injured the public interest in the existence of accurate market information and in ensuring public confidence in financial reporting of publicly traded companies.
- 126. As a direct and proximate result of the Defendants' foregoing breaches of fiduciary duties, Defendants acted willfully and contrary to the best interest of the Company. As a result, the Company has sustained damages.

- A. Determining that this action is a proper derivative action maintainable under law, and that demand is excused;
- B. Awarding, against all Defendants and in favor of the Company, the damages sustained by the Company as a result of Defendants' breaches of their fiduciary duties;
- C. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its investors from a recurrence of the damaging events described herein;

- D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
 - E. Granting such other and further relief as the Court deems just and proper.

FOURTH CAUSE OF ACTION

Against All Defendants for Gross Mismanagement

- 127. Plaintiff incorporates by reference and re-alleges each allegation contained in Paragraph 1-126 above, as though fully set forth herein.
- 128. By their actions alleged herein, Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of the Company in a manner consistent with the operations of a publicly held corporation.
- 129. As a direct and proximate result of Defendants' gross mismanagement and breaches of duty alleged herein, the Company has sustained significant damages in excess of millions of dollars.
- 130. Because of the misconduct and breaches of duty alleged herein, Defendants are liable to the Company.

- A. Determining that this action is a proper derivative action maintainable under law, and that demand is excused;
- B. Awarding, against all Defendants and in favor of the Company, the damages sustained by the Company as a result of Defendants' breaches of their fiduciary duties;
- C. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, to comply with the Company's existing governance

obligations and all applicable laws and to protect the Company and its investors from a recurrence of the damaging events described herein;

- D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
 - E. Granting such other and further relief as the Court deems just and proper.

FIFTH CAUSE OF ACTION

Against All Defendants for Unjust Enrichment

- 131. Plaintiff incorporates by reference and re-alleges each and every allegation set forth in Paragraphs 1-130 above, as though fully set forth herein.
- 132. By their wrongful acts and the omissions of material fact that they caused to be made, Defendants were unjustly enriched at the expense of, and to the detriment of, the Company.
- 133. During the Relevant Period, Defendants either received bonuses, stock options, or similar compensation from the Company that was tied to the financial performance or artificially inflated valuation of the Company or received compensation that was unjust in light of Defendants' bad faith conduct.
- 134. Defendants were aware of, or realized, the benefits of the unjust enrichment that they received to the detriment of the Company.
 - 135. It would be inequitable for Defendants to retain said benefits.
- 136. Plaintiff, as a shareholder and a representative of the Company, seeks restitution from Defendants and seeks an order from this Court disgorging all profits, benefits, and other compensation, including any performance-based or valuation-based compensation, obtained by Defendants due to their wrongful conduct and breach of their fiduciary duties.

- A. Determining that this action is a proper derivative action maintainable under law, and that demand is excused;
- B. Awarding, against all Defendants and in favor of the Company, the damages sustained by the Company as a result of Defendants' breaches of their fiduciary duties;
- C. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its investors from a recurrence of the damaging events described herein;
- D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
 - E. Granting such other and further relief as the Court deems just and proper.

REQUEST FOR RELIEF

- A. Determining that this action is a proper derivative action maintainable under law, and that demand is excused;
- B. Awarding, against all Defendants and in favor of the Company, the damages sustained by the Company as a result of Defendants' breaches of their fiduciary duties;
- C. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its investors from a recurrence of the damaging events described herein;
- D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: February 9, 2017

NEUBERGER, QUINN, GIELEN, RUBIN & GIBBER, P.A.

By: /s/ Cynthia L. Leppert

Cynthia L. Leppert (Bar Number 05857)

One South Street, 27th Floor Baltimore, MD 21202

Telephone: (410) 332-8529 Facsimile: (410) 332-8594 Email: <u>CLL@NQGRG.com</u>

Attorneys for Plaintiff

OF COUNSEL:

GAINEY McKENNA & EGLESTON

Thomas J. McKenna Gregory M. Egleston 440 Park Avenue South New York, NY 10016 Telephone: (212) 983-1300

Telephone: (212) 983-1300 Facsimile: (212) 983-0380

Email: tjmckenna@gme-law.com
Email: gegleston@gme-law.com

Attorneys for Plaintiff (Motion for Admission Pro Hac Vice to be filed)